PRESENTATION TO THE EPA: CHEMICAL SAFETY AND POLLUTION PREVENTION

Hopefully all have read our prior email to Assistant Administrator Dunn on Nov 5, 2020. If not, please do and understand the broad concern from Scientific to Ethical that deserves to be considered in the context of standards.

For science there is but one standard, proof. For ethics, we rely on great deliberative moments like Nuremberg and Helsinki that protect humans from intentional and unintentional atrocities by requiring informed consent where experimentation affects them.

Neither standard should be dismissed, but to the contrary, should be ever present in how product experimentation is considered, evaluated, administered and judged.

I could begin with a lengthy discussion of Oxitec's history that demonstrated contempt across the spectrum of science and ethics standards at many points, such as releasing GM Mosquitoes without proper disclosure and engagement with the community affected in the first three countries experimented on, resulting in the Gate Foundation revoking grant funding at the time and a "not welcome sign" for Oxitec in each of these countries.

Or, we could start with the pattern of beguiling marketing misrepresentations or lies, used to replace truth as they push for profitability, shockingly even under oath to congress in 2016.

We surely think the EPA should wonder if they have been shown truthful and comprehensive information Oxitec is aware of; especially considering how they lied on the 2017-18 EUP Application for the OX513A, regarding the their ability to mechanically sort females and males, claiming 1/4300 respectively, when their most recent year long trial data in the Cayman showed performance no greater than 1/500. How many times does someone need to deceive you before the burden of proof become higher?

Not surprisingly the Securities and Exchange Commission (SEC) has found Precegen, the new name for Intrexon, the most recent prior parent of Oxitec, guilty of falsifying data to dupe investors and improve market value. Much more will be learned as the class action lawsuits are ramping up. This pattern is nearly identical to Oxitec behind the scenes and in public. Numerous very clear example of this can be seen in the "Freedom of Information" style released emails from Dr Alan Wheeler, Chief Scientist for the Cayman Mosquito Research and Control Unit (MRCU), who oversaw the most recent Cayman trials, that ended with the MRCU taking emergencies measure to suppresses what some had called and "explosion of mosquitoes". Clearly, the number of females being released participated in the failure of this experiment, but as Dr John Norris, Chief of Staff for the Lower Keys Medical Center, will tell you, as an eyewitness, Oxitec displayed questionable competence in many areas. Dr Wheeler's team call out Oxitec for breaching scientific protocol, when they chose to use selective samples

114 W PIPPIN DR
ISLAMORADA, FL 33036
WWW.FKEC.ORG

to suggest suppression numbers as high as 96%. 96% suppression versus "explosion of mosquitoes", who's telling the truth?

Roy Bailey's emails and lobbying efforts in behalf of Oxitec with the EPA, are clearly on record, showing significant interest in attempting to revoke the 2017 EUP for Mosquito Mate and the Florida Keys Mosquito Control District (FKMCD). Oddly enough, a simple Wolbachia trial in the Keys in 2017 still has not had data released by the EPA for publication, or any limited commercial use permitting provided. It is difficult to not speculate there may be a link between those political persuasions, in contrast to science and the absence of the data release or commercial approval of the Aedes Aegypti version of the Wolbachia technology; especially since a limited commercial use permit already exists for the Aedes Albopictus version and Expanded Experimental use continues in California for of the same Aegypti technology. Did the lack of approval prevent consideration of the Mosquito Mate Wolbachia technology in any alternatives analysis that would have been done as part of approving the OX5034 EUP?

We could also ask about the numerous redactions in the Environmental Risk Analysis (EUP Doc XXX-0359), hidden under the guise of thinly veiled propriety information claimed by Oxitec, where, for example, the protected information could be used to understand the level of allogeneic risk by utilizing the SDAP(Structural Database of Allergenic Proteins). This important protein information was provided for the OX513A and like so many other questionable places where information was obfuscated, withheld, or provided after it was essential for credible and insightful comments during this EUP approval process, we wonder why?

Time does not permit a truly robust review of the concerns, irregularities, misrepresentation, nonchalant subjective decisions, like assuming 500 eggs tested is a significant sample sizes for 1 billion eggs or more, to be place in the wild. But it should!

In light of the peer reviewed study by Zhoa, et. Al., published in June 2020, Genetic breakdown of Tet-off conditional lethality system for insect population control, place against the termination clause in Director Richard Keigwin's letter of April 30, 2020 (EPA EUP No. 93167-EUP-2), the conditions for termination have been scientifically proven and the EUP should be revoked and further investigation of this product required before any testing in the wild considered. Not only is the establishment of surviving females proven, but the florescent marker systems used as a safeguard to determine no GM Mosquitoes remain in the wild, is clearly unreliable. Such clear failures of this technology amidst the calming reassurance from Oxitec that everything is perfect, compels a review of the veracity and historical accuracy of information provided by Oxitec to all Health and Human Services Agencies, to establish a standard of review by which information provided by this applicant must be verified.

Like the FDA, the EPA has tried to avoid the more difficult work necessary to instill public confidence and fulfill, what the public believes the agencies role to be, "protection" of the community and resources from harmful products. By trying to use existing regulations to

evaluate products as complex as germ-line edited species the potential for harm is greatly amplified. Such methods are in conflict with guidance from the WHO and intellectual leaders in this field recommending against proceeding due to the clear lack of knowledge and investigation into issues like off target mutations and their present, evolutionary and interactive outcomes that could occur in wild release testing. Again, science is about proof, not belief and assumptions. Permitting such risk without sufficient quantitative scientific rigor and addressing the ethical implications on the public is nothing short of negligence.

If you, your children, those you love, some with highly compromised conditions in the middle of a pandemic were forced to be part of this without any opportunity to be properly informed and to avoid being subjected to this experiment, would you be confident no harm would occur, tomorrow, a month or a year from now, or maybe 10 years from now. What do you know? What have you proven? What hasn't been investigated that should?

In the very first college physics class I took the professor started by asking "how many forces are acting on this chair?" No one got them all. Actually, thinking back one was never mentioned, light, photons. I force but so easy to miss, since they do no harm, you don't feel them and they simply provide benefit for us to see, until they are formed into a laser that we now use regularly to cut steel and do eye surgery. Small, insignificant, unimportant, harmless, maybe not so much?

Our agencies should not be affected by profit motive and instead resist these as distractions from the goals of our regulatory agencies, especially when forwarded with political prowess, or inuendo. Our citizens expect our agencies to hold a precautionary principle of proving safety. Look at the current data on people willing to take a vaccine for COVID. Not even 50% of the public at this point has express willingness to take a vaccine, partly driven by fear of short cuts in the evaluation and further driven by a lack of understanding what RNA based genetic vaccines mean.

It is time for the EPA to recognize the non-transparency of this technology and poorly defined risks submitted by this applicant. The standards and procedures for evaluating this level of genetic modification technology do not exist within this agency or any other. By deciding that an expertly designed evaluation method is required to properly understand the risk and performance of this type of technology and proceeding through that regiment, the EPA will have taken a first step in forging appropriate standards and guidelines, for our citizens and the world. Standards that include both scientific proof and ethical process standards for any test.

The absence of ethical process standards in the drive to execute this test in the Keys have demonstrated how easy bias and distortion can enter in. The community of Key Haven is a clear example of informed consent, where the community said "NO". Without sufficient time and the opportunity to see both sides of these consequential discussions, the public becomes confused, anxious and at risk.

We ask the for the immediate termination of the OX5034 EUP, based on a scientifically proven breach of the termination criteria set forth by the EPA. We also ask that any subsequent submission by this applicant for any genetically modified species require a higher level of objective and scientifically rigorous review in light of the repeated mistakes, misrepresentations, assumptions and extended questionable behavior demonstrated.

More universally, as a prudent precautionary standard, all germ-line edited species should, for the foreseeable future, be required to submit to an Environmental Impact Statement level of evaluation process. Without the EPA committing to a sufficient level of scientific rigor that many experts in this field are calling for, the undiscovered and unforeseen consequences could be irreversible and greatly exceed any benefits ever perceived. Why would the EPA take that risk?

Thank you for your time. We are pleased to answer any questions you may have.

Barry Wray
Executive Director